

vehicle, wherein the protein is chosen from SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:26.

4 ~~28~~. (New) A purified Bone Morphogenetic Protein-12 related protein characterized by the ability to induce the formation of tendon/ligament-like tissue, wherein the protein is chosen from SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:26.

REMARKS

Upon entry of this Amendment, claims 17, 18, 20, and 29 are pending in the application. Claim 27 is cancelled, without prejudice. Claim 20 is amended to recite SEQ ID NOs in proper format and to correct a typographical error. New claim 29 is added to more distinctly claim certain embodiments of the invention. Claim 29 is fully disclosed in the specification and in original claims 14 and 17. Accordingly, no new matter is added by this amendment nor should the amendment necessitate any new search or undue consideration by the Examiner. Applicants submit that this Amendment should allow for immediate action by the Examiner.

The Examiner objected to claim 20 for being dependent on a rejected base claim. Applicants respectfully point out that claim 20, as filed, and as amended on January 30, 2003, is an independent claim. In light of this fact, Applicants request that the objection to claim 20 be withdrawn.

The Examiner objected to claim 27 as being a substantial duplicate of claim 18. Claim 18 has been cancelled, removing the grounds for this objection.

In the last Office Action, the Examiner rejected claims 17, 18, 20, and 27 under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claims 6-10 and 17-20 of U.S. Patent No. 6,027,919. Applicants file herewith a terminal disclaimer under 37 C.F.R. §1.321(c) indicating that the '919 patent and the instant application are commonly owned. Applicants note that any patent issuing from this patent would expire on December 7, 2013, well before the expiration date of the '919 patent on February 22, 2017. The terminal disclaimer is submitted solely to confirm that any patent issuing from this application will be enforceable only for and during such period that it and the '919 patent are commonly owned. Applicants respectfully request that, in view of the terminal disclaimer, the rejection of the claims as unpatentable over the '919 patent be withdrawn.

The Examiner rejected claims 17, 18, and 27 under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to provide enablement for the recited BMP-12 related polypeptides when limited only by the names of the polypeptides. The Examiner contends that claims 17, 18, and 27 encompass mutants and/or variants of the BMP-12 related peptides, but the specification fails to set forth the sequence requirements necessary for the tendon inducing activity. Applications respectfully traverse this rejection.

The specification sets forth, at page 15, lines 7-32, a number of possible variants of BMP-12 related proteins and methods for making these variants. Some variants are naturally occurring, while others are deliberately engineered. Example 5 (pages 46-47) provides a well-known assay for the tendon and/or ligament-inducing activity of BMP-12 related proteins. Additionally, the specification describes the various naturally occurring cleavage products of BMP-12 related polypeptides at page 9, line 21-page 10, line 4

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and page 10, lines 25-30. It is well within the skill of one in the art to test the naturally occurring or synthetic variant polypeptides of the invention for tendon and/or ligament-inducing activity in the assay disclosed in Example 5.

The specification also provides specific methods for modifying the glycosylation pattern of the BMP-12 related polypeptides by alteration of specific glycosylation sites. These modified polypeptides may also be assayed for tendon and/or ligament-inducing activity by the assay of Example 5. Therefore, the specification does describe and enable mutants and variants of BMP-12 related proteins having the ability to induce tendon and/or ligament-like tissue growth.

The application provides all the guidance necessary for one skilled in the art to make variant or modified BMP-12 related polypeptides and easily test the tendon and/or ligament inducing activity of these variant or modified polypeptides without undue experimentation. The scope of the claims is supported by the disclosure, as demonstrated by the detailed descriptions of modified BMP-12 related proteins and methods for making the disclosed modifications. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 17, 20, 27, and 29 in condition for allowance. Applicants submit that neither the amendment to claim 20 or the addition of claim 29 raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Finally, Applicants submit that the entry of the amendment would place

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the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

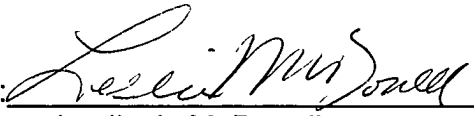
Accordingly, Applicants request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Applicants do not believe that any extension of time is required to enter this Amendment. However, in event of an error, please grant any extensions of time required to enter this Amendment and charge any required fees to deposit account 06-0916.

Respectfully submitted,

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Dated: June 2, 2003

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Version of Claims with Markings to Show Changes Made

17. A purified Bone Morphogenetic Protein-12 related protein characterized by the ability to induce the formation of tendon/ligament-like tissue, wherein the protein is chosen from BMP-12, BMP-13, and MP-52.

~~[18. A pharmaceutical composition comprising an effective amount of the Bone Morphogenetic Protein-12 related protein of claim 17 in admixture with a pharmaceutically acceptable vehicle.]~~

20. (Twice Amended) A pharmaceutical composition for tendon/ligament-like tissue healing and tissue repair, said composition comprising an effective amount of a Bone Morphogenetic Protein-12 related protein in a pharmaceutically acceptable vehicle, wherein the protein is chosen from SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:26 ~~[from SEQ ID Nos.: 2, 4, and 26].~~

27. A pharmaceutical composition for tendon/ligament-like tissue repair, said composition comprising an effective amount of Bone Morphogenetic Protein-12 related protein in a pharmaceutically acceptable vehicle, wherein the protein is chosen from BMP-12, BMP-13, and MP52.

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29. (New) A purified Bone Morphogenetic Protein-12 related protein characterized by the ability to induce the formation of tendon/ligament-like tissue, wherein the protein is chosen from SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:26.

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